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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,010	11/27/2001	Stanislaw R. Burzynski	BURG:04910379.0049.NPUS00	9045

7590

07/21/2004

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EXAMINER

JONES, DWAYNE C

ART UNIT PAPER NUMBER

1614

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/995,010	Applicant(s) BURZYNSKI, STANISLAW R.	
	Examiner Dwayne C Jones	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on the remarks of 26APR2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14,15,17-20,22-25,29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29 and 31 is/are allowed.
- 6) ☒ Claim(s) 14,15,17-20 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 14, 15, 17-20, 22-25, 29, and 31 are pending.
2. Claims 14, 15, 17-20, and 22-25 are rejected.
3. Claim 16 cancelled as per the amendment of April 26, 2004.
4. Claims 29 and 31 are allowed.

Response to Arguments

5. Applicant's arguments filed April 26, 2004 have been fully considered but they are not persuasive. Applicant presents the ensuing arguments. First, applicant alleges that because one skilled in the art understands that proteins and oligo-peptides are polymers of amino acids, as is the case with the Jaeger compositions, the instant claims now require that the amino acids are present either as free-form amino acids or as pharmaceutically acceptable salts, rather than as proteins or peptides. Second, applicant argues that the closed "consisting of" language in the instant claims excludes all components from the claimed components, other than the components recited in the claims.

6. First, applicants alleges that because one skilled in the art understands that proteins and oligo-peptides are polymers of amino acids, as is the case with the Jaeger compositions, whereas the instant claims now require that the amino acids are present either as free-form amino acids or as pharmaceutically acceptable salts, rather than as proteins or peptides. This allegation is not found persuasive because the prior art

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reference of Jaeger teaches of a composition of the very same components, namely amino acids and riboflavin. Applicant alleges that because the instant amino acids are in free form, they are patentably distinct from those of the prior art. However, after the prior art composition of Jaeger is administered the body will naturally metabolize proteins and oligo-peptides ultimately into individual amino acids. For this reason, the prior art teaching of Jaeger discloses of the very same components that are instantly claimed, thus rendering the instant invention obvious. Furthermore, Jaeger specifically teaches that the amino acids present are hydrolysable, (see claims 1-4).

7. Second, applicant argues that the closed "consisting of" language in the instant claims excludes all components from the claimed components, other than the components recited in the claims. The fact remains that the prior art discloses of instantly claimed components of contains riboflavin and the amino acids of glycine, alanine, serine, threonine, valine, and arginine, (see claims 1 and 4), which renders the instant composition obvious to one having ordinary skill in the art especially when Jaeger teaches the very same pharmaceutical components.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. The rejection of claims 14, 15, 17-20, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaeger of U.S. Patent No. 4,826,680 is maintained

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and repeated. Jaeger teaches of a pharmaceutical composition that contains riboflavin and the amino acids of glycine, alanine, serine, threonine, valine, and arginine, (see claims 1 and 4). In addition, Jaeger discloses that this composition has excellent immunological properties, and is useful in the treatment of cancer, (see column 1). Jaeger also teaches that this composition contains suitable pharmaceutical additives and carriers, (see column 3, lines 54-62). The instant claims are directed to composition claims with an intended use of a composition consisting of riboflavin, arginine, and alanine, glycine, serine, threonine, and valine. The prior art reference of Jaeger also teaches of a composition that contains the very same components that are instantly claimed. The only distinction between the prior composition and the instant invention lies with the transitional language of the phrase "consisting of " in the instant application and "comprising" claim language as disclosed by Jaeger. Even though the instant composition employs the use of the "consisting" claim language, the prior art reference of Jaeger specifically teach and provide motivation to use riboflavin in the presence of , arginine, and alanine, glycine, serine, threonine, and valine in order to make pharmaceutical preparations.

Allowable Subject Matter

10. Claims 29 and 31 are allowed.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

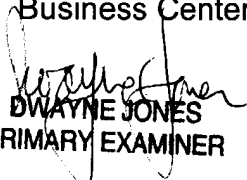
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Thursday, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (703) 872-9306.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair-direct.uspto.gov>. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).


DWAYNE JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
July 19, 2004